

Appl. No. : 10/038,730
Filed : January 2, 2002

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

32-41, 43, 44, 46, 53-57, and 59, i.e., all the pending claims

Identification of Prior Art Discussed

Evans (USP 5,702,361); Slepian (USP 5,634,946); Murayama (USP 5,891,192)

Proposed Amendments

Applicants suggested amending claim 32 to recite that the biologically active material is infused in the polymer precursor and that the biologically active material is differentiated from the polymer precursor.

Principal Arguments and Other Matters

The present claimed subject matter is directed to a polymer precursor having a biologically active material infused therein. Cited art is directed to a polymer precursor without any additional biologically active material.

Results of Interview

Though agreement was not reached, the Examiner suggested that the proposed amendment strategy would potentially overcome the rejections over the cited art.

REMARKS

Applicants sincerely thank the Examiner for the courtesy he extended Applicants' representative during the telephonic interview of June 1, 2006.

Applicants have amended claim 32. No new claims are added, nor any claims deleted. Accordingly, Claims 32-41, 43, 44, 46, 53-57, and 59 remain pending.

The present amendments add no new matter and are fully supported by the specification as initially filed. Support for the amendments is found throughout the specification, and specifically at page 11, lines 5-8 (for pharmaceutically acceptable solvent); and page 7, line 4 to page 11, line 3 (showing separate biologically active component and polymer-forming, or dissolved polymeric, biodegradable material in the pharmaceutically acceptable solvent).

Applicants have considered all of the objections and rejections raised in the Office Action of April 4, 2006 and respond fully below.

Rejections under 35 U.S.C. § 102(e)

Claims 32, 33, 38, 39, 53-55, and 59 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Evans (USP 5,702,361). Applicants respectfully traverse.

Evans is directed to introducing a non-particulate agent, such as a coil or a stent, into a vascular site, introducing a polymer composition to that site, and forming a solid precipitate. The formation of the polymer over the non-particulate agent restricts blood flow and causes clot embolization of the blood vessel. See, for example, Evans, column 9, lines 19-33. The Examiner argues that Evans' polymer is biologically active because it causes blood to clot.

Applicants respectfully point out that the system of claim 32 comprises, in addition to a polymer precursor, or a dissolved polymer, and a mechanical occlusive device, a biologically active component. This component is separate and distinct from the vaso-occlusive polymer forming, or dissolved polymer, material. Applicants respectfully submit that the presence of all three separate components in the claimed system was clear in the claims previously submitted, especially in view of the specification, which describes the polymers and the bioactive materials under separate headings, beginning on page 7. However, in order to clarify the distinction between the polymers and the bioactive materials more explicit, Applicants have amended claim 32 to recite the polymer-forming, or dissolved polymeric, biodegradable material in element a), the biologically active component in element b), and the mechanical occlusive device in element

c). Further, claim 32 has been amended to explicitly recite that the polymer-forming, or dissolved polymeric, biodegradable material is dissolved in a pharmaceutically acceptable solvent, in which the biologically active component is also dissolved.

Applicants respectfully submit that Evans does not teach the presence of a separate biologically active component. The system disclosed in Evans comprises only of a non-particulate agent and a polymer composition. Applicants respectfully submit that because at least one element of claim 32 is not present in the cited reference, the reference does not anticipate claim 32. Because the remaining claims incorporate, either directly or indirectly, the limitations of claim 32 by reference, Applicants respectfully submit that Evans does not anticipate any of the pending claims. In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(c).

Rejections under 35 U.S.C. § 103(a)

Claims 32 and 34-36 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Evans in view of Slepian (USP 5,634,946). Applicants respectfully traverse.

The difference between Evans and the presently claimed subject is discussed above. Slepian teaches a method similar to that of Evans, except with different polymeric materials. Slepian does not teach the presence of a third and separate biologically active component. Therefore, the references, either alone or in combination, fail to disclose a limitation of the pending claims, namely the biologically active component.

In addition, Applicants respectfully submit that Evans and Slepian, either alone or in combination, fail to motivate or provide expectation of success for adding a biologically active component to the polymeric material taught by these references.

Further, claims 32, 40, 41, 43, 44, and 46 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Evans in view of Murayama (USP 5,891,192). Applicants respectfully traverse this rejection as well.

Murayama teaches coating intraluminal implants with a protein by dipping the implant into a protein solution and allowing it to dry. Murayama, column 1, lines 57-60 and column 4, lines 1-20. Murayama does not teach combining the subject protein with a polymer or a polymer-forming, or dissolved polymeric, biodegradable material. Thus, Murayama does not teach the presence of a third and separate element of the present claims. Therefore, the

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references, either alone or in combination, fail to disclose a limitation of the pending claims, namely the presence of a polymer-forming, or dissolved polymeric, biodegradable material.

Applicants respectfully submit further that Evans and Murayama, either alone or in combination, fail to motivate or provide expectation of success for adding the polymeric material to a biologically active component taught by Murayama.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

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CONCLUSION

Applicants have amended claim 32. Claims 32-41, 43, 44, 46, 53-57, and 59 remain pending. Applicants have endeavored to respond to all of the Examiner's rejections and objections raised in the Final Office Action of April 4, 2006. Applicants respectfully submit that the claims as amended herein are patentable and should be passed to issue. A notice to that effect is respectfully requested.

No fee is believed due with respect to this response. If this is incorrect, please charge any required fees, including any fees for extension of time, to Deposit Account No. 50-1105. Applicants invite the Examiner to call the undersigned if any issue can be resolved through a telephonic discussion.

Respectfully submitted,

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